S/N 09/400,365IN THE UNITED STATES PATENT AND TRADEMARK OFFICEPATENT

Applicant: Charbel, et al.

Examiner: Jones, Hugh M.

Serial No.: 09/400,365

Group Art Unit: 2123

Filed: September 20, 1999

Docket: 01566.002US1

Title: Patient Specific Circulation Model

DECLARATION OF DR. DAVID J. LANGER UNDER 37 C.F.R. § 1.132

1. I, David J. Langer, received an M.D. from the University of Pennsylvania School of Medicine in 1991. After doing an internship in general surgery from 1991-1992, I was a resident in neurological surgery from 1992-1998 at the Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania. From 1998-1999, I was a Neurovascular Fellow at the Institute of Neurology and Neurosurgery at Beth Israel North Medical Center. I am currently a practicing neurosurgeon with medical licensure in New York and Pennsylvania and specialty certification by the American Board of Neurological Surgery. I have authored numerous publications in the fields of neurology and neurological surgery and currently hold a faculty appointment as Assistant Professor of Neurological Surgery at the Albert Einstein College of Medicine and a hospital appointment as Attending Neurosurgeon at the Institute of Neurology and Neurosurgery Beth Israel Singer Medical Center.
2. I have reviewed the poster abstract entitled "Validation and Clinical Potential of a Computerized Model of the Cerebral Circulation," by Fady T. Charbel, M.D. et. al. The abstract appears to describe a clinical study in which a computerized model of the cerebral circulation was used to simulate the circulation of 114 patients before and after a cerebral vascular procedure. The model was validated qualitatively (by neurological examination and outcome) and semi-quantitatively (by TCD and SPECT) in 32 of the 114 patients who did not undergo open surgery. In 82 of the 114 patients, a surgical procedure was performed which allowed direct flow measurements to be made during the surgery for validating the computer model. The abstract states that the clinical outcomes and semi-quantitative test results were consistent with the predictions of the model in all patients. In the 82 patients who underwent open surgery and in whom direct vessel flow measurements were made, the flows predicted by the model and the flows measured during surgery were found to be linearly correlated, both at baseline and after performance of the vascular

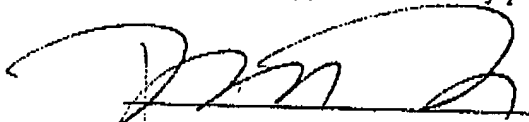
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remodeling procedures. It appears to me that the phrase "vascular remodeling procedures" as used in the abstract unambiguously refers to the surgical reconstructive procedures performed on the patients. Furthermore, I find nothing in the abstract to suggest that there was any kind of corrective procedure being applied to the computer model to account for differences between predicted and measured flows.

3. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the statements are made with the knowledge that willful false statement and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

8/20/01
Date


David J. Langer, M.D.